

Arkansas Laboratory Sentinel Monitoring Network

Self-Reported Deficiencies in Arkansas County Health Unit Laboratories

1993-2000

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Introduction

With the publication of the Institute of Medicine Report on medical error, "To Err is Human," a focus has been placed on the cause and prevention of medical error. A key factor to understanding error is to identify the types of problems that occur, and where in the diagnostic and treatment process they occur.

Errors in medical testing can be envisioned as systematic errors which, by providing incomplete or inaccurate information, transform themselves into poor decisions and subsequent adverse patient events. Much of the research on laboratory quality has focused on the accuracy of the analytical results produced by the clinical laboratory. However, this is only one area in which an error can occur. Errors in the pre- and post-analytical handling of laboratory data can also compromise the data. For example, Howanitz and Cembrowski¹ found that 3.5% of elevated calcium results were not documented, and over 20% had no clinical follow-up. A series of studies have found that actual analytical errors involve less than 10% of all errors, with pre- and post-analytical errors constituting the remainder.^{2,3,4} For example, one study has found that error rates on laboratory requisition slips total as high as 18% in some institutions.⁵ As Goldschmidt notes, the conversion of data into useful information is the only thing that counts.⁶ Accurate instrument readings can be compromised by failures in other areas of the testing process.

Self Reporting in ADH Local Health Units

Starting in 1992, the Arkansas Department of Health began the task of becoming accredited by HCFA under the CLIA '88 regulations. One immense problem that faced the quality assurance section was monitoring the quality assurance (QA) activities of the state's 94 local health unit (LHU's) laboratories spread across 75 counties. To make matters more interesting, all 94 LHU's were placed under one CLIA certificate. The 75 counties were further divided into ten administrative areas, with each area containing approximately seven to nine counties. To insure uniformity of testing, a standard operating procedure manual and QA plan was developed disseminated to each LHU. In order to document that the appropriate QA monitoring was performed as described in the QA plan, a form was developed for the LHU's to record which of the 10 CLIA QA conditions were audited, the problems within each condition found during the audit, and the appropriate corrective action taken. These audits were performed on a monthly basis and reported to the PHL QA section on a quarterly basis.

A Microsoft Access® database was developed and used to summarize the audit report by problem and condition, whether or not corrective actions were implemented, and the status of follow-up QA checks related to the problem. As the problems were entered into the database, they were given codes to simplify data entry, for example, "Gram stain control not performed" was given the code "GSC" and placed under the CLIA QA condition of Quality Control. The problems within each condition that were reported and summarized by the QA section on a semiannual basis by region, and then by the

individual LHU's within each area. An annual report was published and made available to all LHU testing staff at the end of each calendar year.

The data was used by QA office to determine the most frequently occurring problems within each of the 10 CLIA QA conditions. Additionally, the data was analyzed to identify problems which occurred with an unusually high frequency within a specific area or LHU. In some cases, additional training was given to assure that the LHU lab staff understood the CLIA requirements for waived and moderate complexity testing. The problem summaries were also given to "CLIA coordinators" within each area. The coordinators worked closely with the LHU lab personnel to assure that appropriate monitoring was occurring and that problems were being documented and corrected. As a result of this monitoring plan, the QA section has a compendium of things that can go wrong in small laboratories performing waived and moderate complexity testing.

Reported deficiencies from this database were reclassified and tallied into five categories: pre-analytical, analytical, post-analytical, quality systems, and safety (Table 1). Pre-Analytical factors were those compromising the result before the patient specimen could be analyzed, and directly affecting the specimen. Analytical deficiencies were those directly affecting the actual testing of the specimen and reporting of the results obtained. Post-Analytical factors were those affecting the use of the data after a report of the results obtained by testing was generated. Quality Systems problems were deficiencies related to general record keeping not directly involved in the testing and reporting process, but indicative of a failure of the quality assurance process. Safety violations were violations of laboratory safety guidelines.

Results

While results have varied from year to year, the largest fraction of reported deficiencies occurs in the analytical, post-analytical, and record-keeping areas. From 22-47% (mean 33%) of noted deficiencies have occurred in areas related to the testing process, and 14-37% (mean 36%) in the post-analytical phase. Similarly, 13-33% (mean 23%) of reported deficiencies occur as generalized failure of the quality system. Pre-analytical and safety deficiencies are relatively rare. (Table 2, Figures 1 and 2) These results differ from the literature in that the rate of analytical problems is higher, and pre-analytical problems are lower. This may occur due to the fact that the LHU testing staff consists largely of nurses rather than medical technologists, must utilize paper rather than electronic medical records, have a high turnover rate which means many employees are unfamiliar with agency procedures and CLIA requirements, and are at times understaffed who may be technically less proficient at testing activities than personnel such as medical technicians in other environments. Most other studies have occurred in more formal laboratory environments, which are more likely to be staffed by laboratory staff with formal laboratory training

In more recent years, the total number of reported deficiencies has risen. Whether this has occurred as a result of increasing acceptance of the reporting system or through actual

increases in the occurrence of error is unknown, although the former is suspected. As this system has been implemented, it has been adapted and refined to make it more user-friendly. Because it is a self-reporting system, and the units report only the finding of a deficiency in a quarter, not the gross number of deficiencies, this is indeterminate.

As a tool, the self-audits have been a successful mechanism for identifying and addressing problems. The lab staff at the local health units have worked very hard to correct the problems cited. These surveys are the primary mechanism for oversight of the remote laboratory sites, and have played a key role in bringing the units into compliance and maintaining their certification. They serve both as a compliance tool and as a device for training the unit medical staff, primarily nurses, on the quality assurance requirements for compliance. Since CLIA '88 was implemented, only a few minor deficiencies cited by the CLIA surveyors. The units were able to maintain this high standard of patient care in spite of staff shortages and high turnover rates.

Table 1. Examples of Deficiencies

Pre-Analytical

Problems with specimen collection
Documentation of collection
Improper specimen identification

Analytical

Controls not performed
Maintenance not performed
Calibration not performed
Data not recorded
Defective kits or reagents
Proficiency testing or quality control testing failures
Facility problems (room temperature, etc)
Samples rejected due to out-of control QC
Instrumentation/Incubator/refrigerator failures

Post-Analytical

Results not posted in the patient's medical record
Results in medical record disagree with other records such as the testing log.

Quality System

Temperature logs incorrectly filled out
SOP manual revisions not posted or initialed
CLIA employee documentation incomplete or missing
Problems are not documented

Safety

Body fluid spills
Gloves not worn
Improper disposal

Table 2. Reported Deficiencies, 1993-2000

Type	Year								Total
	1993	1994	1995	1996	1997	1998	1999	2000	
Pre-Analytical	5	3	6	26	10	13	28	18	109
Analytical	33	68	90	129	139	264	471	179	1373
Post-Analytical	56	94	101	118	92	120	144	92	1482
Quality System	48	83	88	43	71	214	292	119	958
Safety	11	12	16	3	7	40	69	27	185
All	153	260	301	319	319	651	1004	435	4107

Percent	1993	1994	1995	1996	1997	1998	1999	2000	Total
Pre-Analytical	3%	1%	2%	8%	3%	2%	3%	4%	3%
Analytical	22%	26%	30%	40%	44%	41%	47%	41%	33%
Post-Analytical	37%	36%	34%	37%	29%	18%	14%	21%	36%
Quality System	31%	32%	29%	13%	22%	33%	29%	27%	23%
Safety	7%	5%	5%	1%	2%	6%	7%	6%	5%

Figure 1

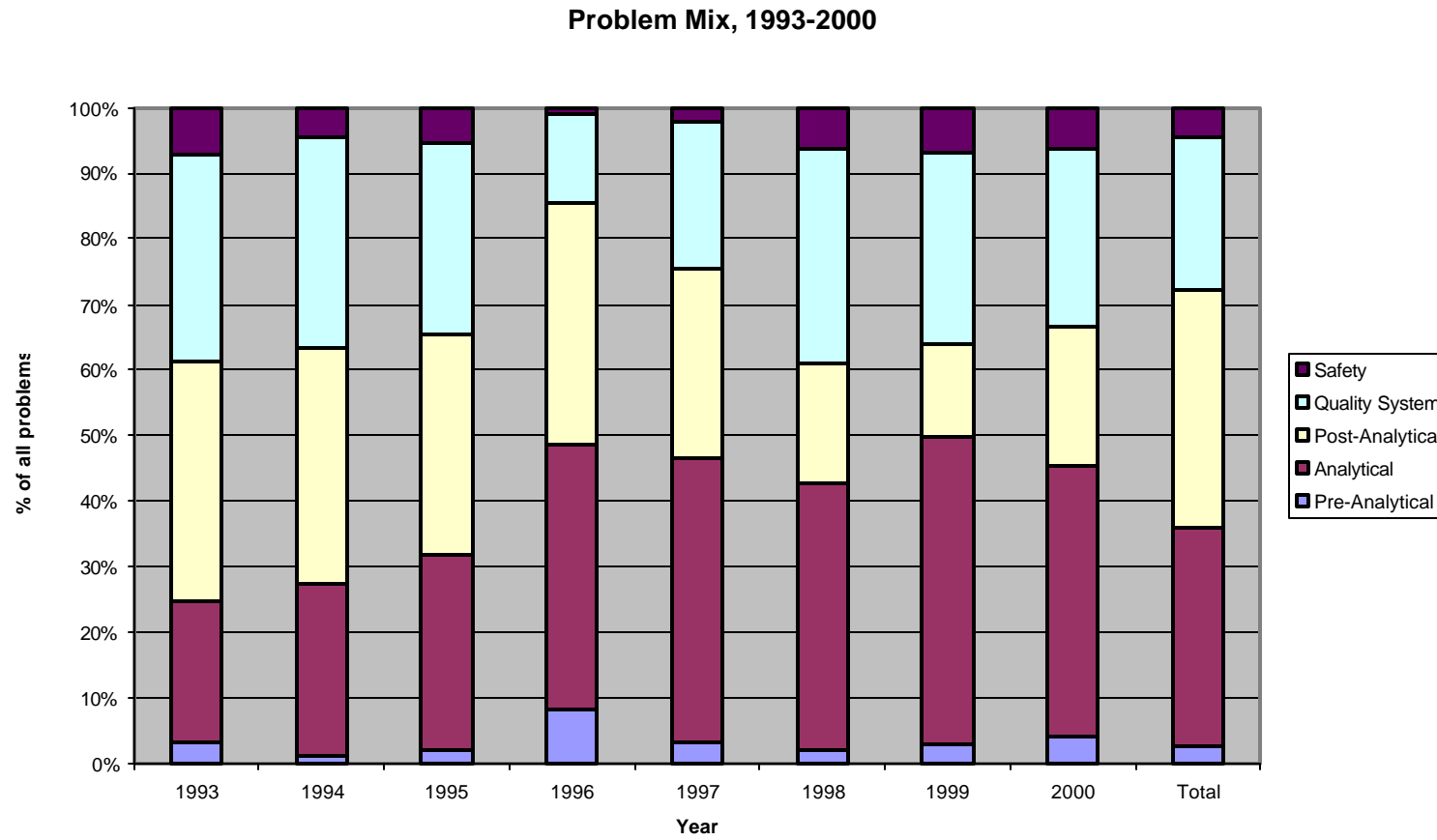


Figure 2

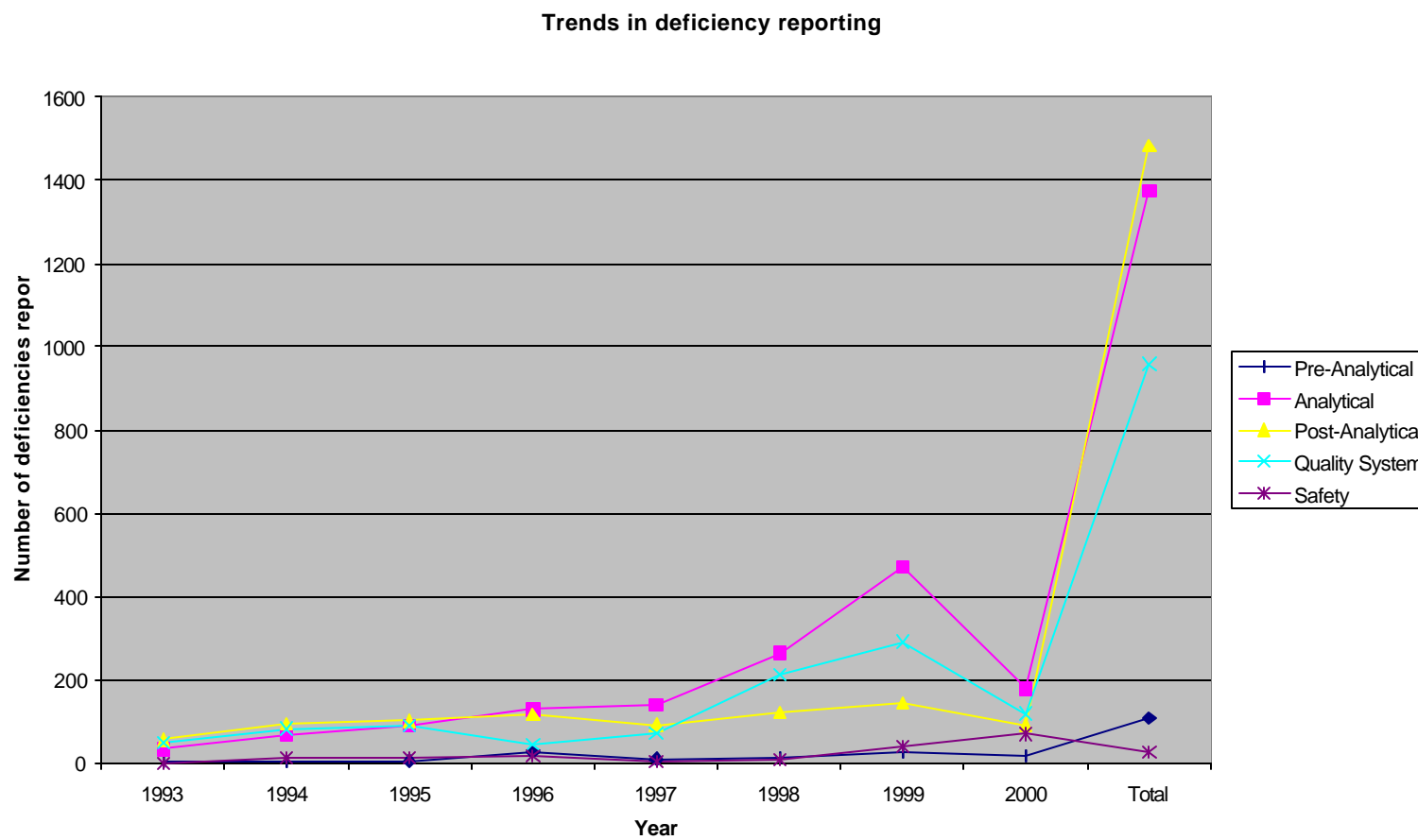
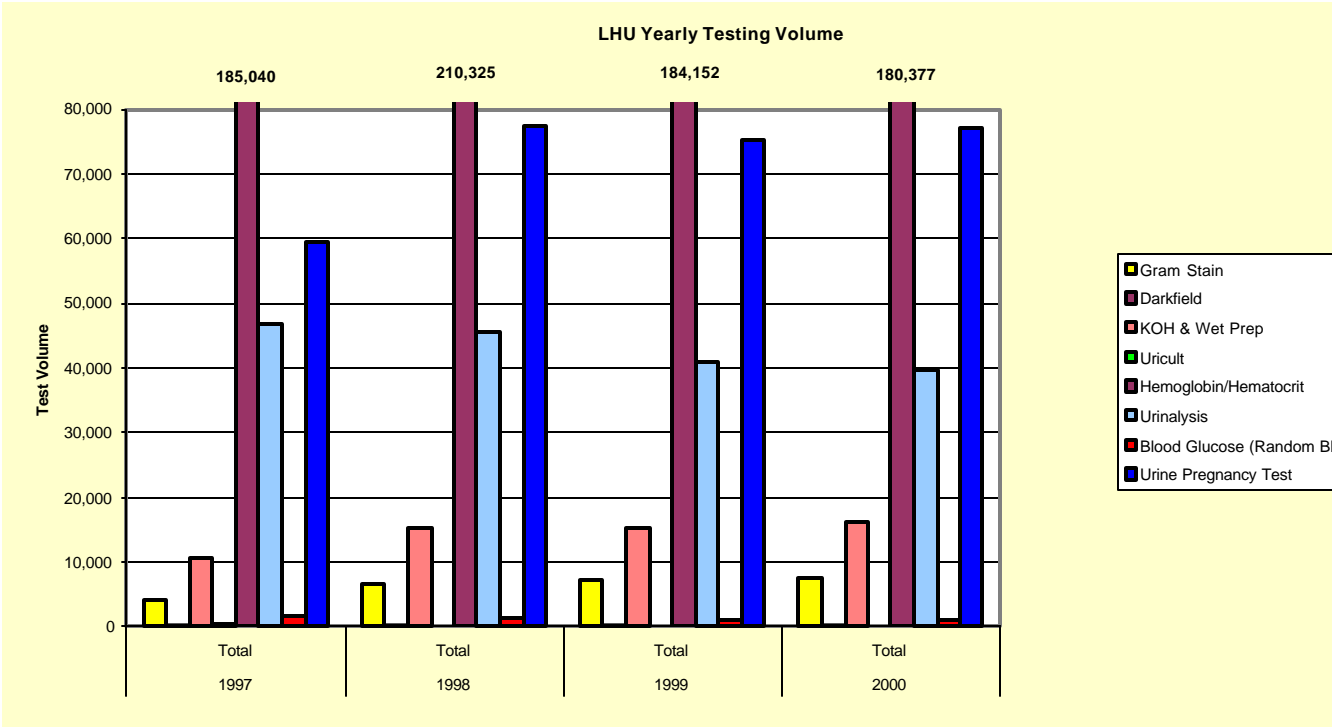


Figure 3



Notes

¹ Howanitz PJ, Cembrowski GS. "Post-analytical quality improvement: A College of American Pathologists Q-Probes study of elevated calcium results in 525 institutions." *Archives of Pathology and Laboratory Medicine*, 2000; 124:504-510.

² Ross JW, Boone DJ. "Assessing the effect of mistakes in the total testing process on the quality of patient care [Abstract 102]". In Martin L, Wagner W, Essian JDK, eds. *1989 Institute of Critical Issues in Health Laboratory Practice*. Minneapolis, MN, Dupont Press, 1991,

³ Plebani M, Carraro P. "Mistakes in a stat lab: types and frequency," *Clinical Chemistry* 1997; 43:1348-1351.

⁴ Boone J, Steindel S, Herron R, Howanitz, PJ, Schiffman RB, Zarbo RB. "Transfusion Medicine" *Archives of Pathology and Laboratory Medicine* 1995; 119:999-1006.

⁵ Valenstein P, Meier F. "Outpatient Order Accuracy: A College of American Pathologists Q-Probes study of Requisition order entry accuracy in 660 institutions." *Archives of Pathology and Laboratory Medicine* 1999; 123:1145-1150.

⁶ Goldschmidt, HMJ. "Postanalytical factors and their influence on analytical quality" *Scandinavian Journal of Clinical Laboratory Investigations* 1999; 59:551-554.